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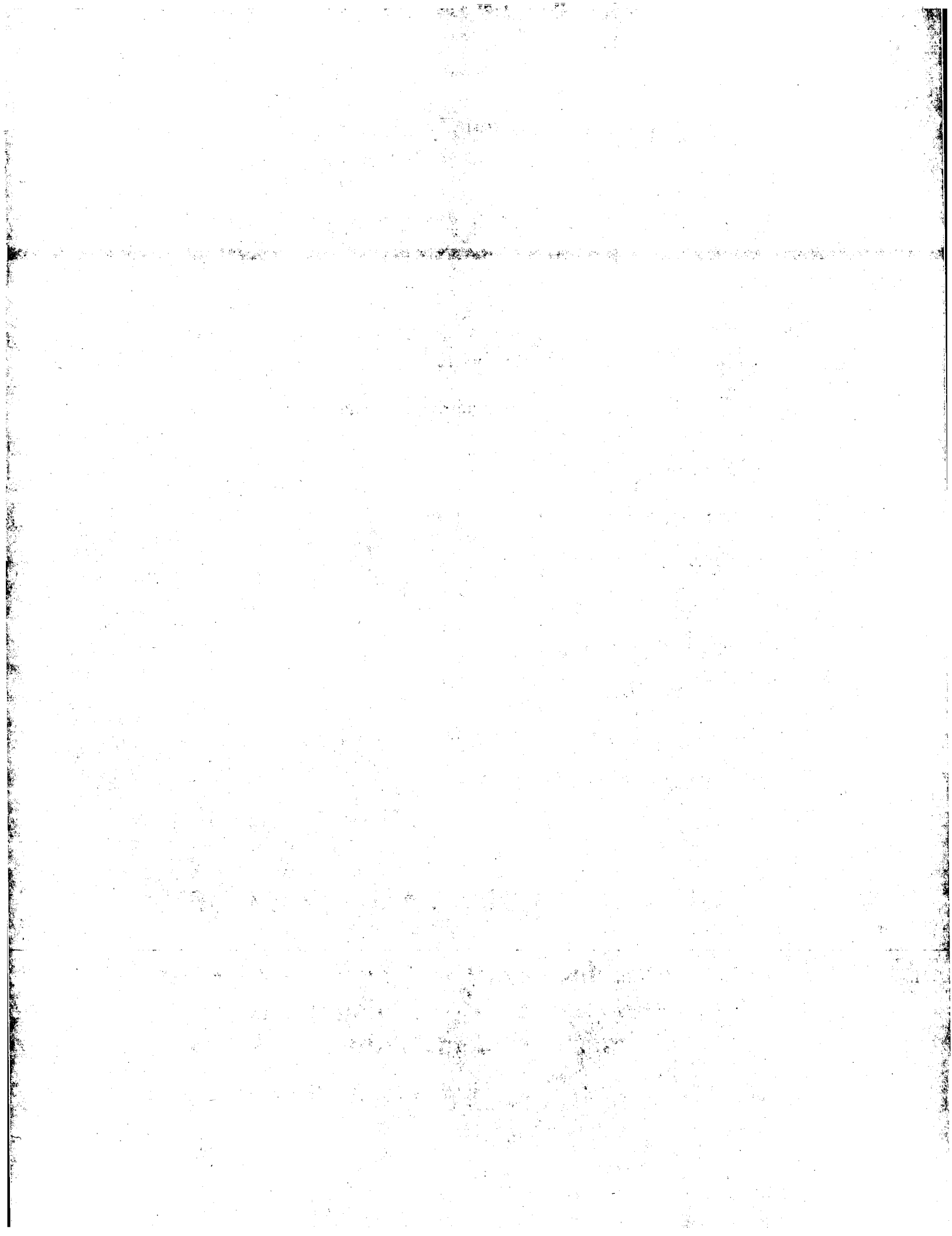
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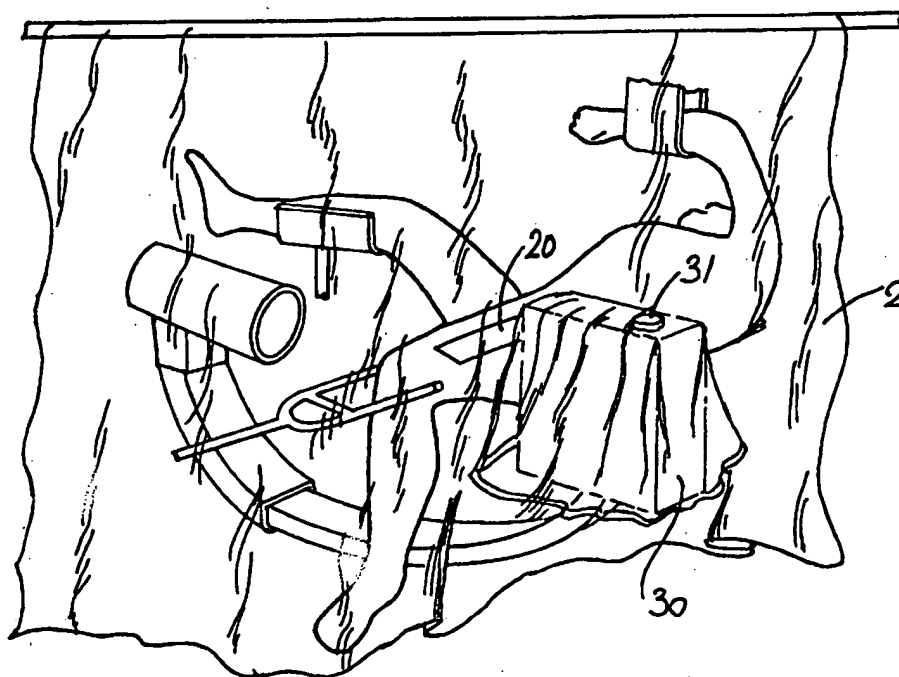
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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/IE96/00032 <b>(22) International Filing Date:</b> 29 May 1996 (29.05.96) <b>(30) Priority Data:</b> S950387 29 May 1995 (29.05.95) IE <b>(71)(72) Applicant and Inventor:</b> RYAN, Rosemary [IE/IE]; No. 1 Summerville Apartments, Convent Road, Athlumney, Navan, County Meath (IE). <b>(74) Agents:</b> O'CONNOR, Donal, H. et al.; Cruickshank & Co., 1 Holles Street, Dublin 2 (IE).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DE (Utility model), DK, DK (Utility model), EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
<b>(54) Title:</b> A SURGICAL DRAPE   <b>(57) Abstract</b> A disposable surgical drape (1) for limb surgery and the like, having a main sheet (2) and a pocket (3). The pocket (3) being formed to allow intermittent access by bulky equipment to an operating site without using additional drapes and without compromising the sterility of the operating site.		

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"A Surgical Drape"Introduction

The present invention relates to a disposable surgical drape for limb and the like surgery requiring the intermittent use of bulky auxiliary operating equipment, the drape being of the type comprising a flexible, sterile micro-organism proof main sheet of non-woven plastics material having an upper surface and a bottom sterile patient contacting surface and a clearly defined operating site.

Such disposable surgical drapes are well known. Indeed, there are many surgical drapes which are provided for limb surgery such as illustrated in European Patent Specification No. 281 331. There are many drapes provided for other specific uses such as disposable drapes for cardio-vascular procedures as described in European Patent Specification No. 186 582 or for the use in procedures requiring exposure of both legs and containment of the perineum such as described in U.S. Patent Specification No. 4,479,492.

However, there is a particular type of operation that causes considerable problems in that in many operations and in particular limb surgery there is a need to use bulky auxiliary equipment during the operation such as an image intensifier, for example, an X-ray machine. This is particularly the case during intra-medullary nailing operations. These are not the only operations where it is necessary to use such equipment which is so bulky that it cannot be left permanently in situ so that the surgeon has to have it removed to allow he or she access to the patient to carry on the operation. This leads to considerable problems in keeping a desired sterile area at

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the correct degree of sterility, where, for example a portion of the auxiliary operating equipment may be moved from a non-sterile area to a sterile area during surgery. It is for example, acknowledged that it is not simply  
5 enough to provide a drape with sufficient material or fabric to allow it to encompass the auxiliary equipment, because the inclusion of an excessive amount of fabric which may hang below the sterile field is liable to become contaminated during use. This problem is identified in  
10 Canadian Patent Specification No. 998589. Another problem with excess fabric is that it may reduce the accessibility of various operating controls when needed during the operation. Thus, as has been acknowledged by Canadian Patent Specification No. 998 589, there is a need to  
15 provide a surgical drape of only sufficient fabric as is necessary to provide sterility during the operation. However, then a problem arises with the use of such bulky auxiliary operation equipment.

Heretofore it has been known for example to have the  
20 disposable surgical drapes which were adapted to allow use, for example of a microscope head unit during an operation which apparatus, such as for example disclosed in U.S. Patent Specification Nos. 3,528,720 and 4,045,118, employed an elongated open sleeve for engaging the  
25 microscope head and auxiliary equipment. The problem with such a unit is that it is difficult to guarantee sterility and secondly it would not work with very bulky auxiliary operation equipment. A solution to this problem was proposed by U.S. Patent Specification No. 4,266,663 where  
30 there is provided a disposable surgical drape of a complicated construction, which drape is formed as to include an adaptor ring to engage for example the lens of a microscope which will correctly retain the drape material at the periphery of an object lens barrel and  
35 which will also provide a rugged base external of the

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draped for ready removable mounting of successive disposable plain parallel protective cover plates as may become soiled in the course of any single surgical procedure. This solution to the problem would work reasonably well for such microscopes, however, it would not work for move bulky auxiliary operation equipment, particularly those that are likely to interfere with the surgeon's operations. It then becomes necessary to move the bulky auxiliary equipment out of the operation area. Various solutions have been proposed and indeed have been used to overcome this problem with varying degrees of success.

Individual drapes of varied sizes were used in the past, however, this was not necessarily satisfactory as there tended to be contact between the unsterilised portion of one drape with the sterilised portion of another. They were often held in place with steel clips or the like which cause puncture wounds in the skin and are now obsolete due to the risk of, for example, HIV infection. Disposable sterile tape is thus used, however, there was still the major problem that sterile areas could come in contact with unsterile areas of the drapes. Another problem was that when moving machinery out of the way such as for example an X-Ray C arm, the sheets generally tended to come apart and render the operation site unsterile. Again, the solution to this was to provide even further sterile sheets, adding considerably to the cost. A further problem was that with all these complicated arrangements of drapes, auxiliary drapes etc. valuable time was wasted in arranging, rearranging, replacing, etc. of the surgical drapes. This added to the length of time of the operation. As well as having increased costs in greater theatre and staff utilisation, there is the added disadvantage to the patient in that it is preferable that operations be completed as quickly as possible.

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As mentioned above a considerable amount of this equipment has to be used in limb surgery for example in intramedullary nailing of bones, where the medical team has to use X-ray equipment and this X-ray equipment has to be moved in and out of the operating site so that the guide drilling and insertion of screws through the distal holes can be correctly achieved. One of the principal ways of doing this is by the technique known as the image intensifier mounted target device procedure. In this procedure, the initial step in targeting is positioning of the image intensifier such that the distal holes in the nail appear correctly which causes the image intensifier to be moved upwards or downwards in a vertical direction. An image intensifier mounted target device is then fitted to a carriage that is mounted on the X-Ray tube side of the image intensifier and after the X-Ray beam is aligned to produce the correct target, the target device is folded down in line with the beam and manoeuvred against the patient's thigh and the screwing operation takes place. For these and other nailing techniques the various pieces of bulky auxiliary operation equipment have to be moved in and out of the area.

Generally speaking surgical drapes have side edges lying along the operating table and the end edges across it that is to say transversely relative to the patient being operated on. Thus, in this specification panels and fold lines substantially parallel to the side edges are identified as being longitudinal and are designated lateral when parallel or substantially parallel to the end edges.

The present invention is directed towards providing a disposable surgical drape which will overcome the aforesaid problems and provide an efficient sterile drape



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for use with bulky auxiliary operation equipment.

Statements of Invention.

Accordingly there is provided a disposable surgical drape for limb and the like surgery requiring the intermittent use of bulky auxiliary operating equipment, the drape being of the type comprising a flexible, sterile micro-organism proof main sheet having an upper surface and a patient contacting bottom sterile surface and a clearly defined operating site, wherein there is provided a pocket in the sheet on one side of the operating site of dimensions sufficient to allow such auxiliary equipment to be moved adjacent to the patient and to be enveloped with the patient underneath the drape, the pocket having an outer surface and an inner sterile equipment contacting surface. The advantage of a separate pocket within the drape means that the problem of excessive material is overcome in that the pocket will not extend the natural area of the drape when in the collapsed position.

Further the invention provides a surgical drape in which the pocket is connected to an extensive opening, cut-out of the main sheet, and is formed by an auxiliary pocket forming sheet secured adjacent the peripheral edge of the opening and releasably secured to the upper surface with its inner sterile surface folded within itself. The advantage of having a large opening is that it is possible to accommodate bulky equipment and at the same time by folding the pocket and securing it on the upper surface of the drape when the bulky auxiliary operating equipment is not in use, the problem identified in, for example, Canadian Patent Specification No. 998,589 of excessive amounts of fabric hanging below the sterile field is overcome.

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In a particularly preferred embodiment of the invention the opening for the pocket is rectangular and the pocket is formed from folding a rectangular sheet about a longitudinal fold line to form two longitudinal panels and cutting away and joining the sheet together at each lateral edge to form a triangular lateral panel, thus forming a substantially triangular pocket in cross-section when its apex formed by the longitudinal fold line is pulled apart from the opening. The advantage of this configuration will be appreciated in that when encompassing auxiliary operation equipment the triangular configuration is particularly advantageous in that while it is encompassing a piece of bulky material the longitudinal panel projects substantially horizontally and the other substantially vertically and since most auxiliary equipment is of generally rectangular shape, this is the ideal shape of pocket to encompass it and is to be preferred to a pocket of laterally transverse section.

Ideally the surgical drape has a pair of releasable connection means provided longitudinally spaced apart on the outer surface adjacent the apex of the pocket and a co-operating pair of releasable connection means provided on the upper surface longitudinally spaced apart from the lateral edge of the opening so that on mutual engagement of the connection means, the inner sterile surface is drawn fully within itself and folded flat against the upper surface. The advantage of this arrangement of connection means is that the pocket is tightly folded within itself and away from the aperture in the surgical drape proper and thus will not foul with the surgeon's body or indeed brush against the patient's body over and above what the drape would normally do.

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Ideally a tape of sterile micro-organism proof reinforcing material is placed along the lateral and longitudinal edges joining the pocket to the opening. The advantage of this is that tearing of the drape is unlikely to occur  
5 when moving the bulky auxiliary operation equipment.

In one embodiment of the invention the operating site is formed by portion of the drape having sterile patient skin contacting adhesive covering the bottom sterile surface thereof, and a plurality of separate removable cover  
10 strips across the adhesive. This is a particularly advantageous construction, because it allows varying lengths of operating site to be chosen, the surgeon simply cutting through as much of the material as he or she deems fit.

15 Ideally the removable cover strips extend beyond the adhesive for ease of removal and ensuring that inadvertently adhesive will not contact a patient's skin other than where desired.

In one embodiment of the invention the surgical drape is  
20 provided with an instrument retaining pocket on the upper surface adjacent the operating site. This is particularly advantageous in that the instrument retaining pocket will ensure that any instruments used will be seen and thus articles retained in the pocket may be viewed through the  
25 transparent material so that the presence of articles in the pocket may be detected by the surgical team to prevent their loss and even more importantly to prevent inadvertently the leaving of any such equipment, instruments, swabs, or the like in the patient's body.

30 In one embodiment of the invention the surgical drape comprises:

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a strip of releasable non-setting adhesive on the top surface adjacent the periphery of the drape for retaining the drape in position during an operation; and

5 a removable cover strip over the adhesive.

The advantage of this is that as much of the surgical drape as is required can be secured to a support pole above the operating table, thus providing vertical isolation and maintaining a sterile area.

10 Ideally the material used is a non-woven plastics material utilising seam welding where required.

In one arrangement the surgical drape has a pair of opposed opposite pockets on either side of the operating site, thereby allowing the surgeon free access to both  
15 sides of the operating site without moving the patient or compromising sterility of the operating site.

In one embodiment the drape further comprises a fluid collection pocket having an inlet and an outlet with a side wall tapering inwardly between the inlet and the  
20 outlet.

In this way fluid from the operating site is efficiently directed from the operating site to the outlet where a suction pump or similar device can remove it.

Preferably, the fluid collection pocket has fastening  
25 means for removably mounting the fluid collection pocket adjacent the operating site.

Ideally, the side wall is formed by two side wall panels and the fastening means is provided by an adhesive band

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covered by a peel away strip on each side wall panel adjacent the inlet.

5 This is particularly beneficial in that it allows a single fluid collection pocket to be supplied with the drape which may be positioned on either side of the operating site by removing the peel away strip.

10 According to one aspect of the invention there is provided a fluid collection pocket having fastening means for removably engaging a surgical drape, the pocket having an inlet, an outlet and a side wall tapering inwardly between the inlet and the outlet, the side wall being formed by two side wall panels and the fastening means being provided by an adhesive band covered by a peel away strip on each side wall panel adjacent the inlet.

15 Detailed Description of the Invention

The invention will be more clearly understood from the following description of an embodiment thereof given by way of example only with reference to the accompanying drawings, in which:-

20 Fig. 1 is a plan view of a surgical drape according to the invention when laid flat;

Fig. 2 is a perspective view of the surgical drape of Fig. 1 with a pocket forming part of the drape pulled away from it;

25 Fig. 3 is a sectional view along the lines III-III of Fig. 1;

Fig. 4 is a cross-sectional view along the lines IV-IV of Fig. 1;

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Fig. 5 is a sectional view along the lines V-V of Fig. 1;

5 Fig. 6 is a perspective view of the surgical drape according to the present invention in one position of use;

Fig. 7 is a perspective view of the surgical drape with a pocket forming part of the drape being pulled apart for reception of the auxiliary bulky operation equipment;

10 Fig. 8 is a perspective view of the drape with the auxiliary operation equipment in use;

Fig. 9 is a perspective view of a fluid collection pocket forming part of the invention; and

15 Fig. 10 is a perspective view similar to Fig. 6 with the fluid collection pocket of Fig. 9 in use.

Referring to the drawings and initially to Figs. 1 to 5 thereof, there is provided a surgical drape indicated generally by the reference numeral 1, manufactured from a flexible sterile micro-organism proof non-woven plastics material forming a main sheet 2 and a pocket 3. The surgical drape 1 has an upper surface 4 and a patient contacting bottom sterile surface 5. The pocket 3 as can be most clearly seen from Fig. 2 is mounted over an extensive rectangular opening 6 in the main sheet 2 and is formed from an auxiliary pocket forming sheet which is substantially rectangular which is folded about a longitudinal fold line to form two longitudinal panels 7 for which the fold line forms an apex 8. The sheet is so cut-away and joined together to form two triangular

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lateral panels 9. The weld seams 10 and 11 are clearly shown in Fig. 2 for the connection to the rectangular opening 6 and the formation of the triangular lateral panels 9, respectively. The pocket 3 has an outer surface 12 and an inner sterile surface 13. A pair of longitudinally spaced apart releasable connection means identified by the reference numeral 14 are provided on the pocket 3 for cooperation with corresponding connection means 15 on the main sheet 2. In this particular embodiment of the invention the connection means 14, 15 are provided by VELCRO strips.

There is also illustrated a clearly defined operating site on the main sheet 2 by a quantity of adhesive 20 on the bottom sterile surface 5 covered by removable cover strips 21 (in this embodiment three) which extend beyond the adhesive 20. A strip of releasable non-setting adhesive 22 is placed on the bottom surface 5 adjacent the periphery of the sheet 2 for retaining the sheet 2 in position during an operation and is preferably provided with a removable cover strip 23. A pocket 25 for instruments is provided.

To fold the pocket and secure the connection means 14 and 15 the apex 8 is pulled upwards and outwards so that the connection means 14 contact the connection means 15. This causes the triangular lateral panels 9 to lie partially laterally and partially longitudinally as illustrated in Fig. 1. The remainder of the panel 9 folds in on itself as can be seen from Fig. 1. The correct orientation of the various portions of panels are illustrated clearly in Figs. 3 to 5.

In use, with the pocket assembled, namely with the connection means 14 and 15 connected, the surgical drape 1 is placed over a patient as illustrated in Fig. 6. When

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it is desired to use the drape 1 to, for example, allow access of an X-ray machine indicated by the reference numeral 30 in Fig. 8, the connecting means 14 and 15 are disconnected as shown in Fig. 3 and the pocket 3 withdrawn so that the bottom portion of the main sheet 2 below the pocket 3 and the pocket itself can be placed over the X-ray machine 30 as illustrated clearly in Fig. 8. Also illustrated in Fig. 8 is an optional removable connection means which may be mounted on the inner sterile surface 13 and used with a cooperating connection means on the X-ray machine 30. This is illustrated by the reference numeral 31. This helps to hold the pocket in position on the X-ray machine 30.

It will be appreciated that the surgeon can operate on the patient as he or she desires and when necessary to use, for example, the X-ray machine 30. It can be wheeled into and out of position by the use of the pocket 3. When the pocket 3 is not required, then the connection means 14 and 15 are reconnected and the pocket 3 folded back into position to lie flat against the sheet 2 thereby preventing accidental disengagement.

Referring now to Figs. 9 and 10 there is illustrated a fluid collection pocket forming part of the invention indicated generally by the reference numeral 50.

The fluid collection pocket 50 has an inlet 51, an outlet 52 and a side wall provided by two side wall panels 53 tapering inwardly between the inlet 51 and the outlet 52. Each side wall panel 53 has fastening means at the inlet 51 provided by an adhesive band 54 covered by a peel away strip 55. The inlet 51 also has a spacer band 56 to keep the side wall panels 53 apart when in use.



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In use, the pocket 50 is moved into a position on one side of the operating site, one of the peel-away strips 55 is removed and the adhesive band 54 attached to the drape 2. During the operation fluid from the operating site flows  
5 into the inlet 51 down along the tapered side wall panels 53 to the outlet 52.

It will be appreciated that by providing an adhesive band on each side wall, the same fluid collection pocket may be positioned on either side of the operating site.

10 While the disposable surgical drape described above was manufactured from a clear plastics material, it is appreciated that any other bacteria free or micro-organism free material such as a suitable impregnated paper could be used. The advantage of using a plastics material is  
15 that all the seams can be easily heat welded. Polythene is a particularly suitable material because of its laser impermeable characteristics.

It is envisaged that the drape may include a thermal insulation layer.

20 It will be appreciated that the disposable surgical drape according to the invention has been described with particular reference to limb surgery, but it may be used for any surgical procedure where such bulky auxiliary equipment is required. For example, the pocket might be  
25 formed to accommodate a particular type of image intensifier for example allowing laser targeting of an X-ray site in orthopaedic surgery.

It will be appreciated therefore that the invention does have certain considerable advantages in that the one  
30 composite drape can be used for such surgery whether bulky auxiliary operation equipment is required or not. The

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present surgical drape covers the whole operating table and surrounding area. It is able to accommodate moving machinery which can then be kept sterile. The great advantage of the construction of drape is that there is  
5 little possibility of contamination from unsterile machines as the pocket receives the unsterile machine and keeps it separate from the patient.

It will be appreciated that the drape may include more than one pocket situated around the operating site and  
10 that the size and shape of the pockets may be adapted to accommodate a wide variety of operating equipment.

It will further be appreciated that the use of a surgical drape described above being essentially a vertical isolation drape is not the only orientation in which the  
15 drape may be used.

The drape may also optionally include additional pockets for holding surgical equipment, and drainage channels or pockets.

It will also be appreciated that the fluid collection  
20 pocket described may be used with any surgical drape and need not necessarily be used with the surgical drape described.

The invention is not limited to the embodiment  
25 hereinbefore described which may be varied in both construction and detail.

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CLAIMS

1. A disposable surgical drape for limb and the like surgery requiring the intermittent use of bulky auxiliary operating equipment, the drape being of the type comprising a flexible, sterile micro-organism proof main sheet having an upper surface and a patient contacting bottom sterile patient contacting surface and a clearly defined operating site, wherein there is provided a pocket in the sheet on one side of the operating site of dimensions sufficient to allow such auxiliary equipment to be moved adjacent to the patient and to be enveloped with the patient underneath the drape, the pocket having an outer surface and an inner sterile equipment contacting surface.  
5  
10  
15
2. A surgical drape as claimed in claim 1 in which the pocket is connected to an extensive opening, cut-out of the main sheet, and is formed by an auxiliary pocket forming sheet secured adjacent the peripheral edge of the opening and releasably secured to the upper surface with its inner sterile surface folded within itself.  
20
3. A surgical drape as claimed in claims 1 or 2 in which the opening for the pocket is rectangular and the pocket is formed from folding a rectangular sheet about a longitudinal fold line to form two longitudinal panels and cutting away and joining the sheet together at each lateral edge to form a triangular lateral panel, thus forming a substantially triangular pocket in cross-section when its apex formed by the longitudinal fold line is pulled apart from the opening.  
25  
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4. A surgical drape as claimed in claim 3 in which a pair of releasable connection means are provided longitudinally spaced apart on the outer surface adjacent the apex of the pocket and a co-operating pair of releasable connection means are provided on the upper surface longitudinally spaced apart from the lateral edge of the opening so that on mutual engagement of the connection means, the inner sterile surface is drawn fully within itself and folded flat against the upper surface.
- 5.
5. A surgical drape as claimed in claim 3 or 4 in which a tape of sterile micro-organism proof reinforcing material is placed along the lateral and longitudinal edges joining the pocket to the opening.
- 15
6. A surgical drape as claimed in any preceding claim in which the operating site is formed by portion of the drape having sterile patient skin contacting adhesive covering the bottom sterile surface thereof, and a plurality of separate removable cover strips across the adhesive.
- 20
7. A surgical drape as claimed in claim 6 in which the removable cover strips extend beyond the adhesive.
- 25
8. A surgical drape as claimed in any preceding claim in which there is provided an instrument retaining pocket on the upper surface adjacent the operating site.
- 30
9. A surgical drape as claimed in any preceding claim which the drape is adapted to receive additional

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surgical aids and retain them on the bottom sterile surface.

10. A surgical drape as claimed in any preceding claim comprising:

5 a strip of releasable non-setting adhesive on the top surface adjacent the periphery of the drape for retaining the drape in position during an operation; and

a removable cover strip over the adhesive.

- 10 11. A surgical drape as claimed in any preceding claim in which the material used is a non-woven plastics material utilising seam welding where required.

12. A surgical drape as claimed in any preceding claim having a pair of opposed opposite pockets on  
15 either side of the operating site.

13. A surgical drape as claimed in any preceding claim further comprising a fluid collection pocket having an inlet and an outlet with a side wall tapering inwardly between the inlet and the  
20 outlet.

14. A surgical drape as claimed in claim 13 wherein the fluid collection pocket has fastening means for removably mounting the fluid collection pocket adjacent the operating site.

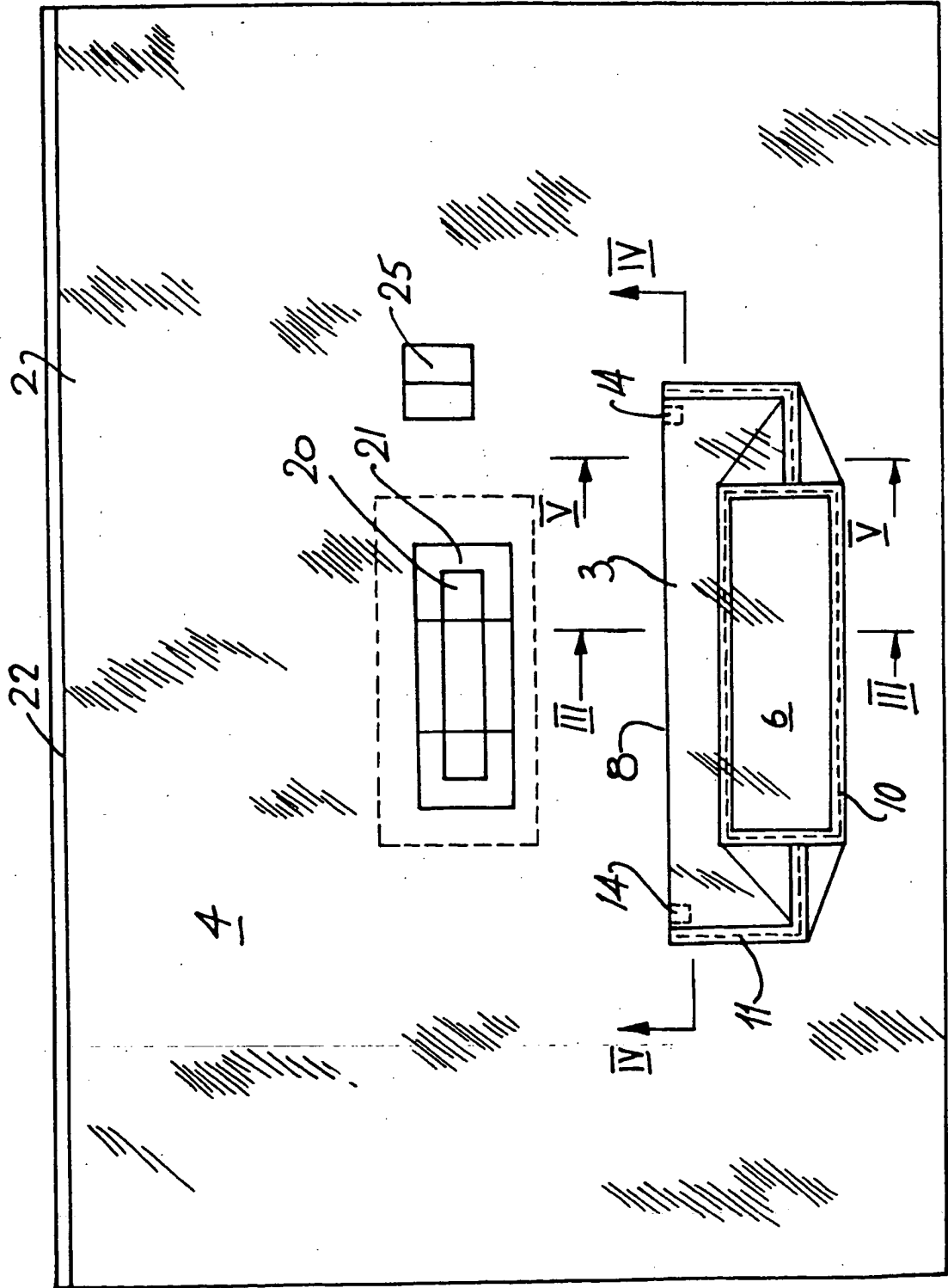
- 25 15. A surgical drape as claimed in claim 14 wherein the side wall is formed by two side wall panels and the fastening means is provided by an adhesive band covered by a peel away strip on each side

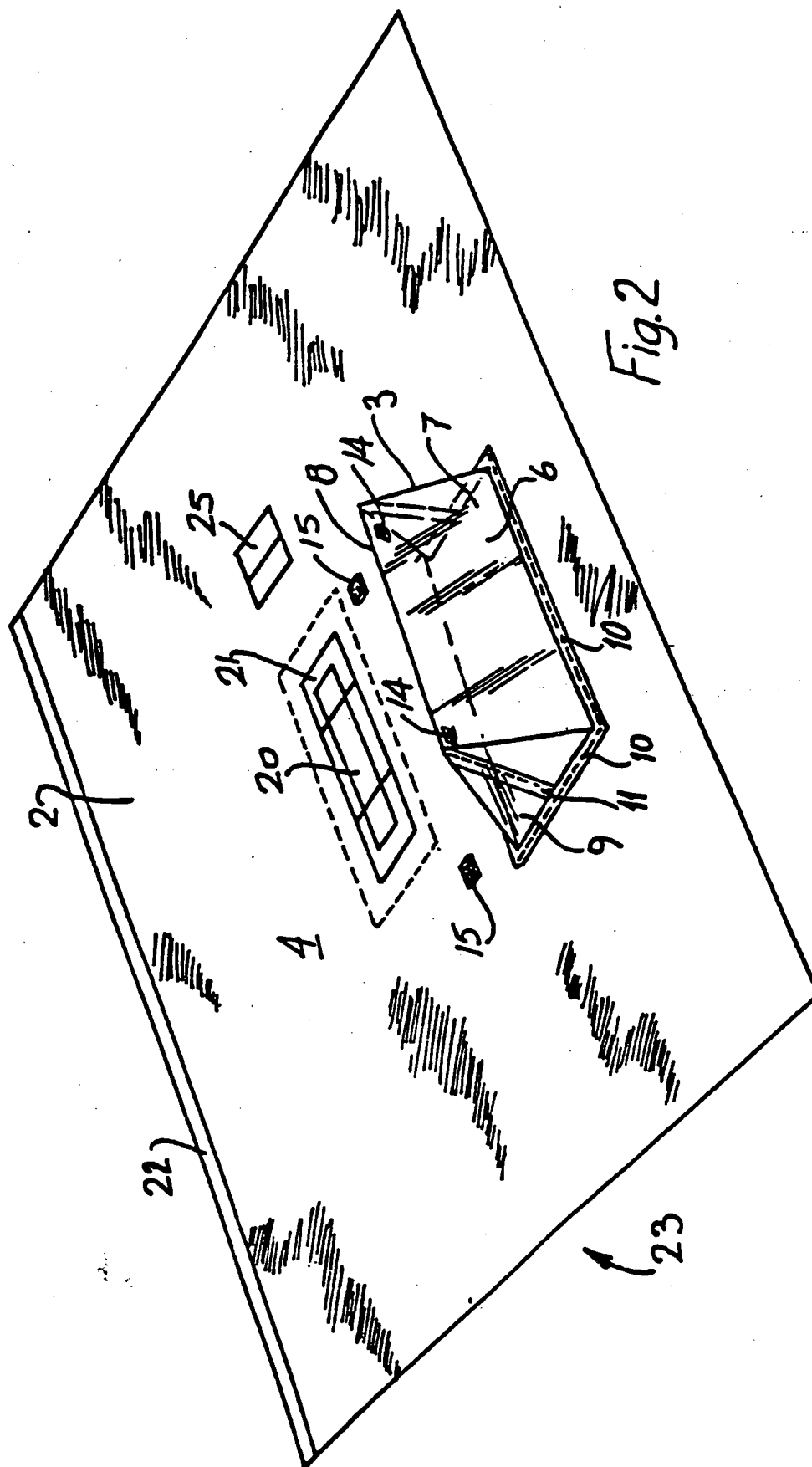
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wall panel adjacent the inlet.

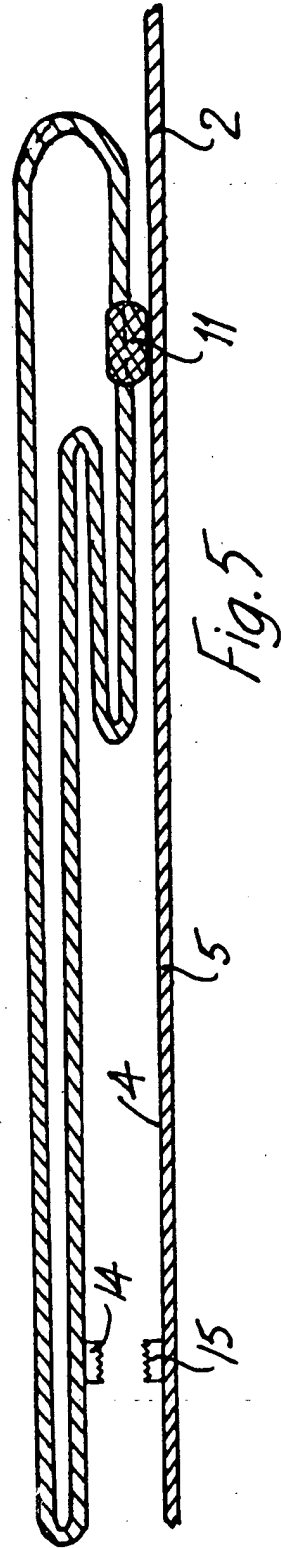
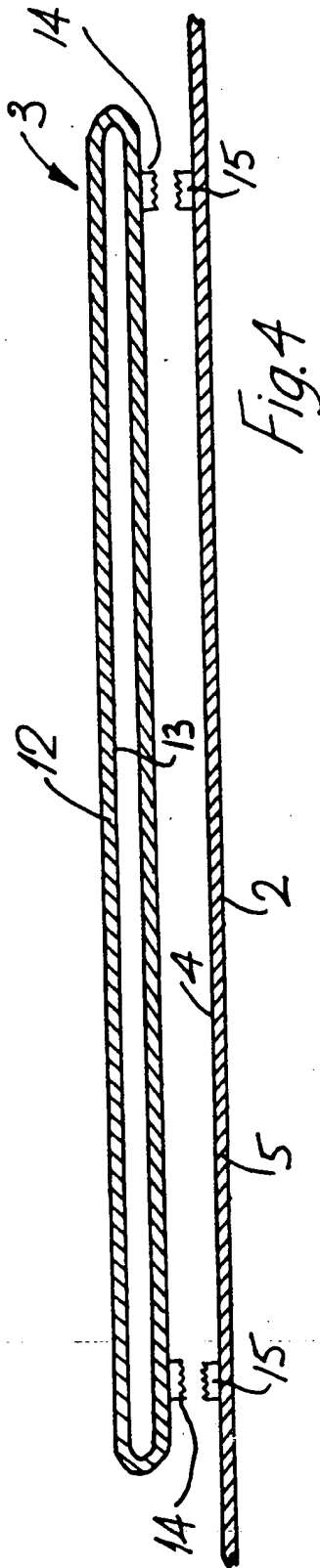
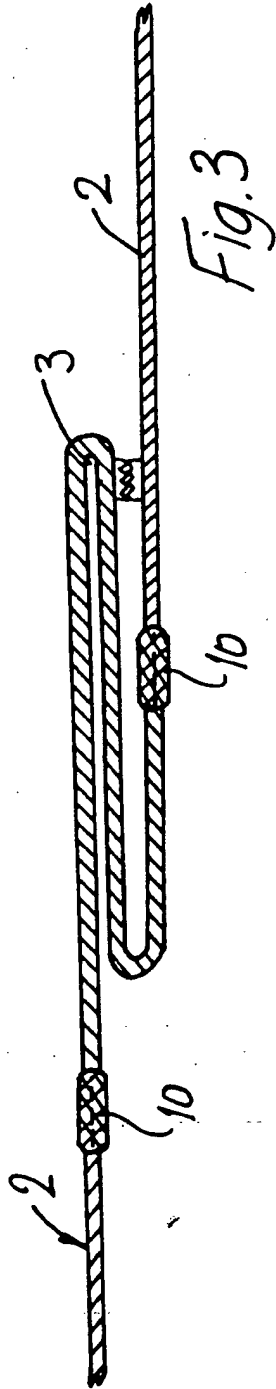
16. A surgical drape substantially as described herein with reference to and as illustrated in the accompanying drawings.
- 5 17. A fluid collection pocket having fastening means for removably engaging a surgical drape, the pocket having an inlet, an outlet and a side wall tapering inwardly between the inlet and the outlet, the side wall being formed by two side wall panels and the fastening means being provided by an adhesive band covered by a peel away strip on each side wall panel adjacent the inlet.
- 10
18. A fluid collection pocket as described herein with reference to and as illustrated in the accompanying drawings.
- 15

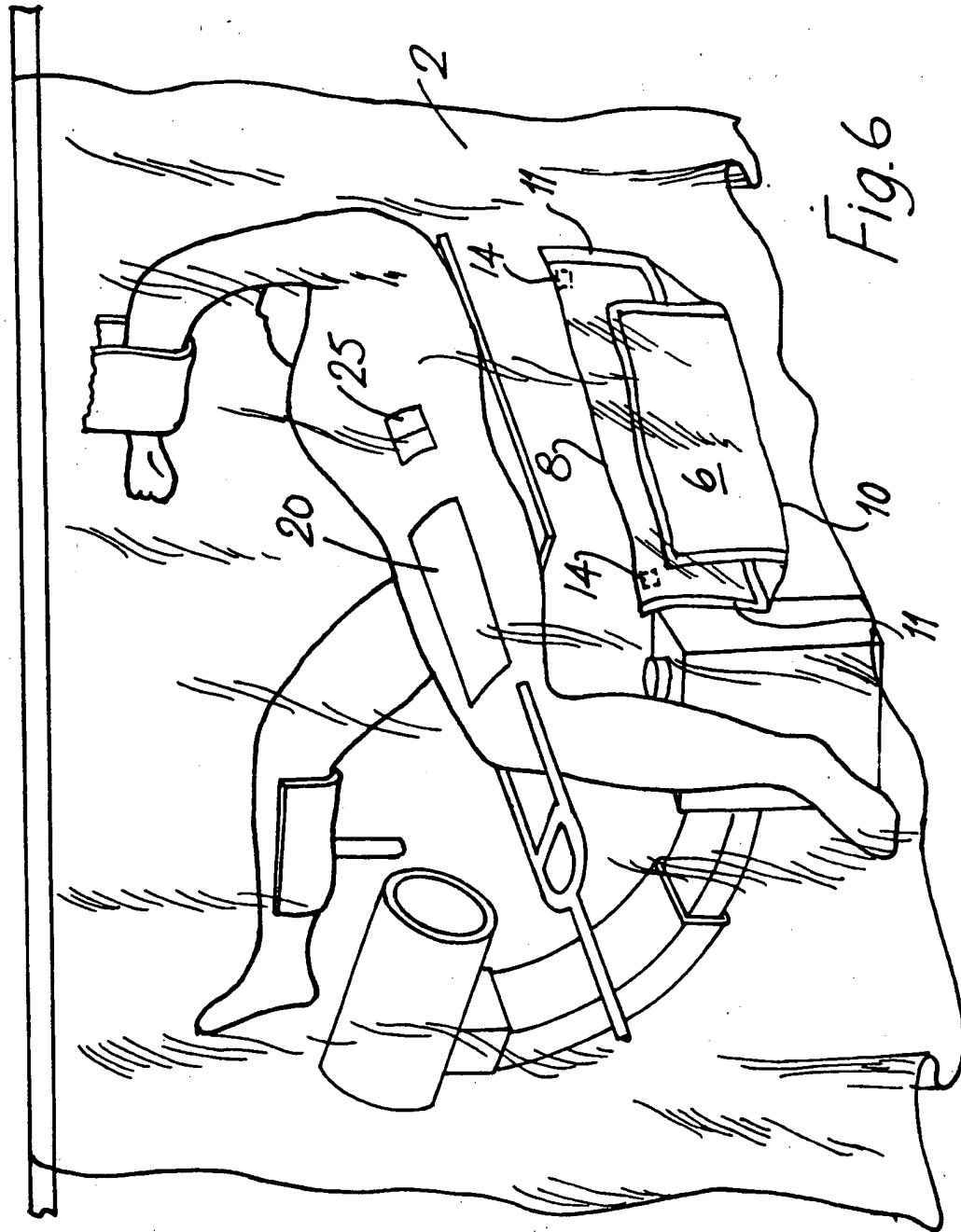
Fig. 1

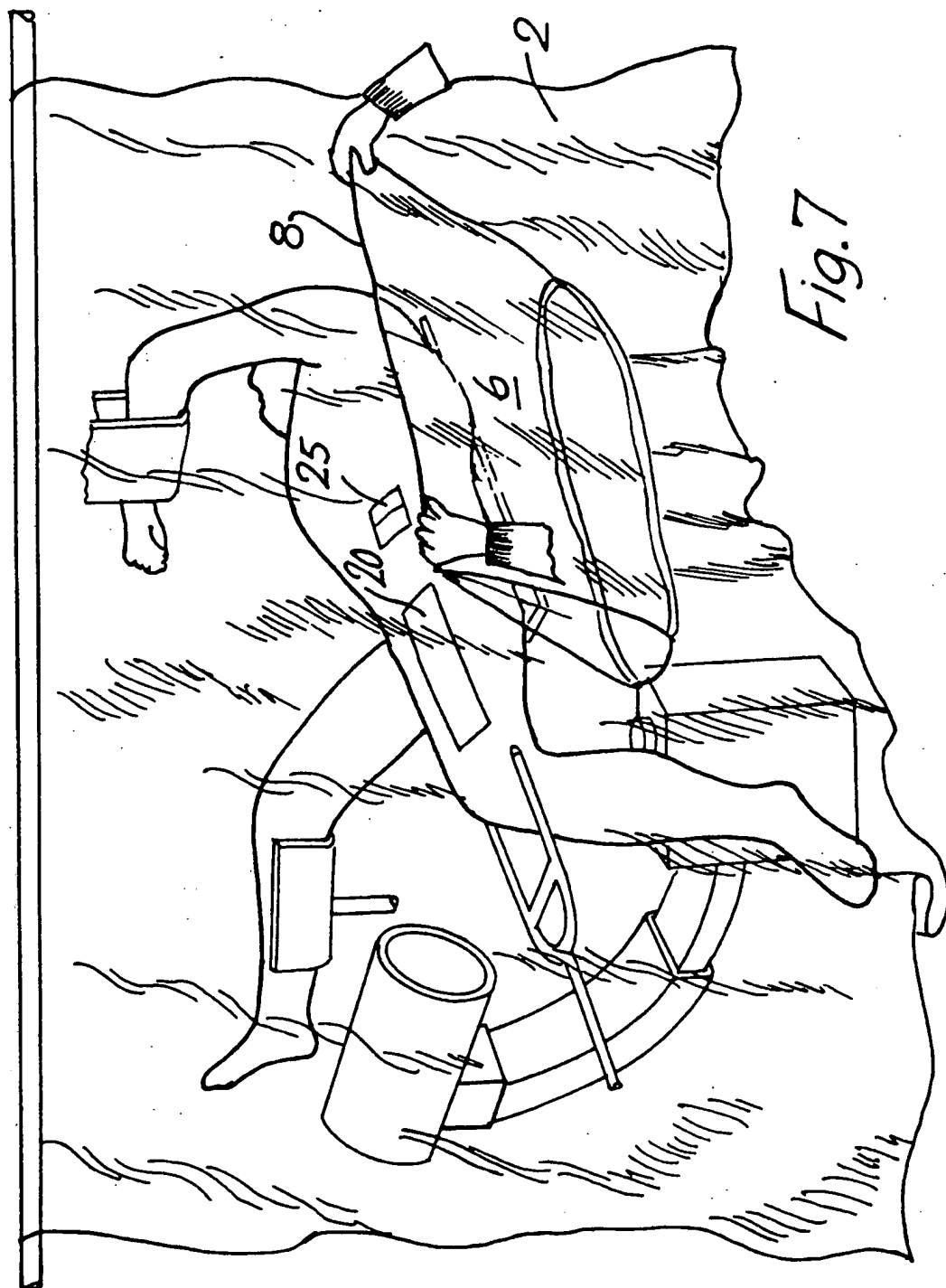


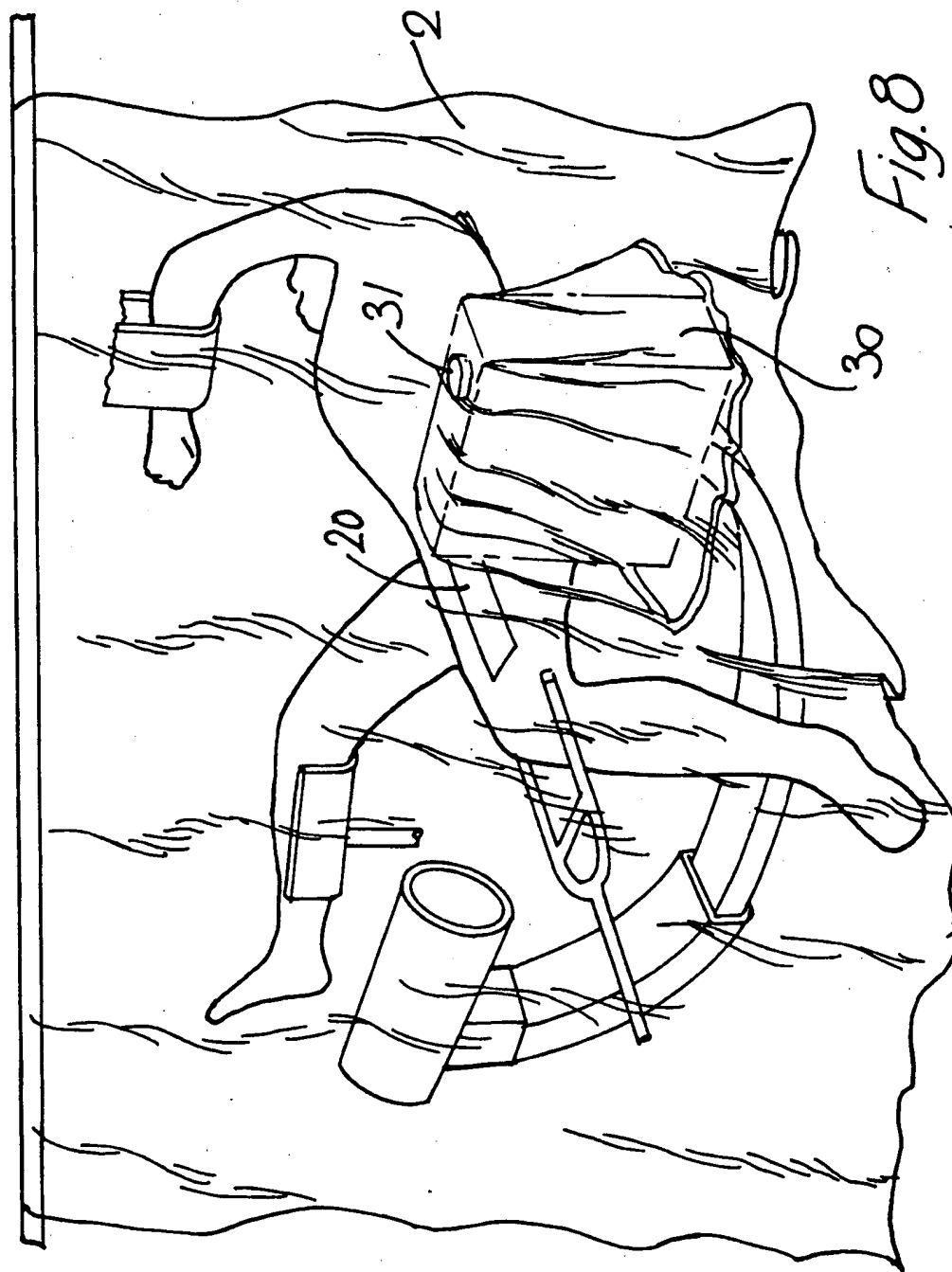


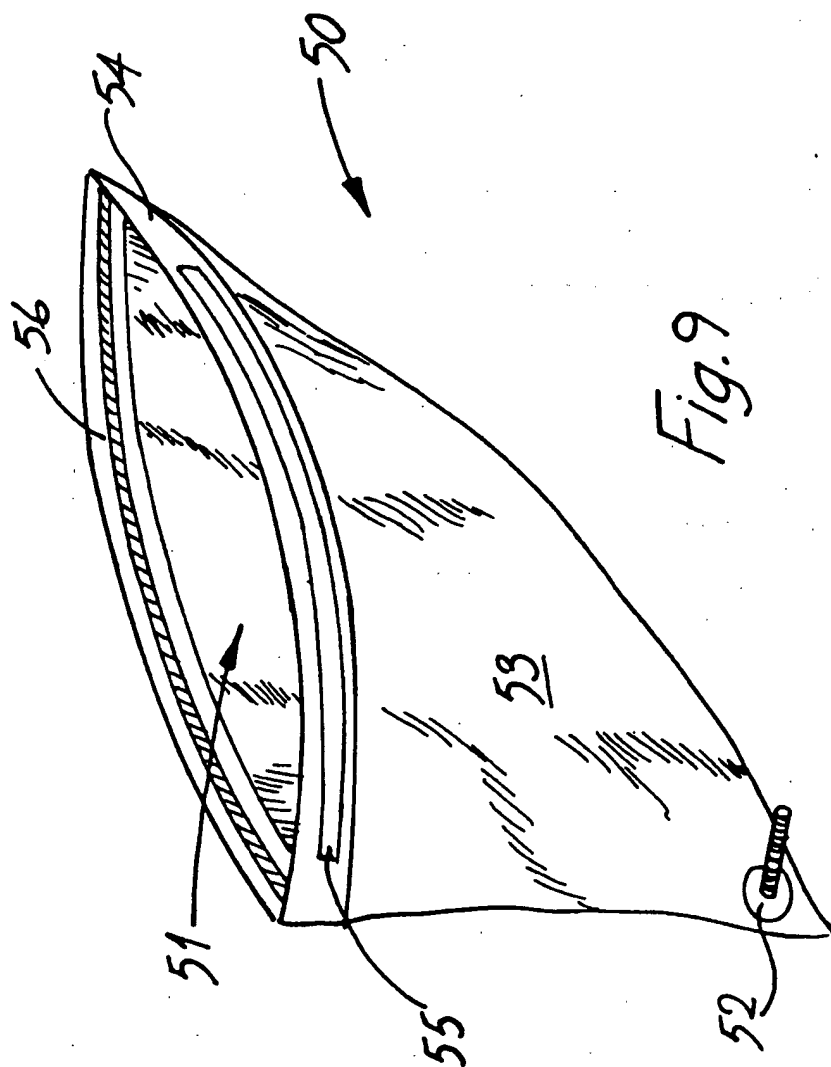


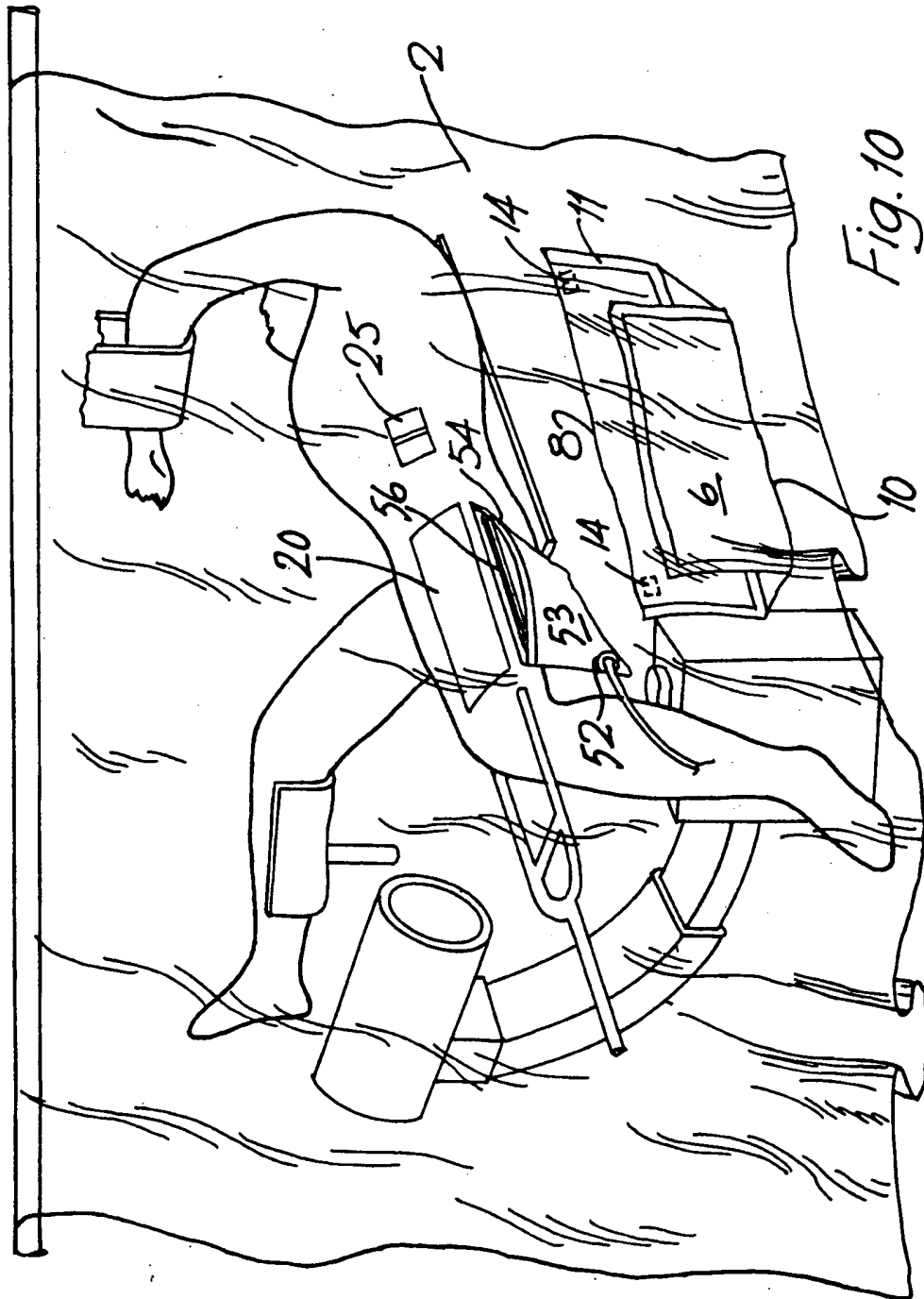












## INTERNATIONAL SEARCH REPORT

national Application No  
PCT/IE 96/00032

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B19/08

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X A	US,A,4 730 609 (MCCONNEL) 15 March 1988 see column 4, paragraph 3 - paragraph 5; figures 1-3 ---	1,6-8,11 2,3
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

11 September 1996

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## INTERNATIONAL SEARCH REPORT

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